UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF SUPPLEMENTAL MOTION TO EXCLUDE AND NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION AND REPLY BRIEF OF MICHAEL THOMAS MARGOLIS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Ethicon") submit this reply memorandum in further support of their supplemental motion to exclude certain opinions of Michael Thomas Margolis, M.D.

INTRODUCTION

Ethicon has moved, in its supplemental memorandum (Dkt. 2833), for exclusion of Dr. Margolis's opinions regarding the alleged defects between mechanically cut mesh and laser cut mesh, as well as his general opinions regarding alleged degradation of Ethicon's mesh products, on the ground that these opinions are unsupported by scientific evidence and are unreliable. (Mem. in Supp. of Defs.' Supp. Mot. to Exclude and Notice of Adoption of Prior Daubert Mot. and Reply Br. of Michael Thomas Margolis, M.D. for Wave 3 ("Defs.' Mem."), Dkt. 2833 at 2). In response, Plaintiffs' primary argument is that Ethicon's arguments "go to the weight of the evidence, not its admissibility" and can be addressed on cross-examination. (Pls.' Mem. in Opp'n to Defs.' Supp. Mot. to Exclude and Notice of Adoption of Prior Daubert Mot. and Reply Br. of Michael Thomas Margolis, M.D. for Wave 3, and Pls.' Notice of Adoption of Mem. in

Opp'n to Prior Daubert Mot. ("Pls.' Resp."), Dkt. 2904, at 1; *see also id.* at 3, 6-7). This displays a fundamental misunderstanding of Rule 702 of the Federal Rules of Evidence: a witness may testify as an expert only if his or her testimony is *based on sufficient facts or data*. Fed. R. Evid. 702. None of Dr. Margolis's opinions regarding mechanically cut and laser cut mesh, nor his opinions on degradation, are based on sufficient facts or data. He should be precluded from testifying as to these subjects in their entirety. Finally, as detailed below, Dr. Margolis's methodology in support of his design defect theories remains flawed, rendering his opinions unreliable and inadmissible.

LEGAL ARGUMENT

I. Dr. Margolis's opinions on mechanically cut versus laser cut mesh are not based on any scientific facts or data; rather, he merely regurgitates internal Ethicon documents.

In its Motion, Ethicon moved to exclude Dr. Margolis's criticism of Ethicon's mechanically cut mesh (MCM) as inferior to laser-cut mesh (LCM) because Dr. Margolis's opinions on this subject were based entirely on his regurgitation of Ethicon's witnesses' depositions and internal Ethicon documents, such as a presentation by Ethicon's engineer and an "internal [Ethicon] memo." (Defs.' Mot. at 3-4). In its ruling on Dr. Margolis's testimony for Wave 1 cases, this Court explicitly precluded Dr. Margolis from parroting what was in Ethicon's corporate documents. (Dkt. 2681, at 12).

In response, although they weakly protest that Dr. Margolis does not "merely parrot[]" internal Ethicon documents, Plaintiffs fail to offer *any* scientific evidence that would support the admissibility of Dr. Margolis's opinions on MCM and LCM. They simply claim that this Court has supposedly previously permitted Dr. Blavias to opine based on Ethicon's internal documents and, therefore, it should allow Dr. Margolis to do so in this case as well. (Pls.' Resp. at 2 (citing *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 6911, 722 (S.D. W. Va. 2014)).

In *Huskey*, however, Dr. Blavias rendered the independent opinion that the transobturator approach used to implant the TVT-O increased the risk of certain injuries, relying on Ethicon documents in support of his opinion. 29 F. Supp. 3d at 722. This Court ruled that "whether an expert may rely on particular information is a different question from whether an expert's opinion has a reliable basis." *Id.* In other words, the Court allowed Dr. Blavias to rely on the documents for the purpose of explaining his opinions. In the present case, Dr. Margolis has demonstrated no personal familiarity with MCM versus LCM that forms the basis of his opinions; rather, his opinions regarding MCM and LCM in his reports consist *solely* of repeating what is in internal Ethicon documents or reiterating the testimony of Ethicon witnesses. (Defs.' Mot. at 3-4). A jury does not need Dr. Margolis to tell it what is in Ethicon's documents or what its witnesses said. *Miller v. Stryker Instr*., 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012) (excluding Dr. Parisian because "much of [her] report regurgitates facts that should be submitted directly to the jury" and she provided "no analysis or explanation" of her conclusory assertions). And the Court has explicitly barred Dr. Margolis previously from doing so. (Dkt. 2681, at 12.)

Knowing that Dr. Margolis's testimony is mere regurgitation not in support of any independent opinion, Plaintiffs scramble to save it by arguing that Ethicon's internal documents corroborate "[Dr. Margolis's] own experience in the field." (Pls.' Resp. at 2). Curiously, however, they follow this assertion not with an example of Dr. Margolis's own experience with LCM versus MCM, but with yet another citation to what Ethicon's engineer has said about MCM/LCM. (*Id.*). Indeed, the only "experience" Dr. Margolis offered in his report is "I personally have witnessed the same type of deformation of the mesh material, *i.e.*, curling, roping/twisting, narrowing and fraying when I have been called upon to remove mesh months or years after implantation." (Defs.' Mot. at 5). Not only is this "experience" not about the

difference between MCM and LCM, specifically, it is also the kind of unverifiable personal experience that this Court has previously rejected as unreliable under Rule 702. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 604–05 (S.D. W. Va. 2013), on reconsideration in part (June 14, 2013) ("Dr. Zolnoun's first general causation opinion is therefore based on nothing more than her personal, unscientific observation and opinion that 'it's obvious' that mesh arms are sharp and can serrate or tear nerves. This is the type of 'subjective, conclusory approach that cannot reasonably be assessed for reliability' and that Rule 702 is designed to exclude."). Dr. Margolis's opinions on the difference between LCM and MCM are solely corporate-document regurgitation, wholly unreliable, and inadmissible under this Court's previous ruling and Rule 702.

II. Dr. Margolis's opinions on degradation do not have scientific support.

In its Motion, Ethicon argued that the scientific articles upon which Dr. Margolis relies in support of his degradation opinions are unreliable, specifically, an article by Sternschuss, G., et al., to which Plaintiffs have specifically pointed in previous waves. (Defs' Mem. at 5-6). Dr. Margolis is not a biomaterials expert.[1] (*See* Mem. in Supp. of Mot. to Exclude Certain Ops. Of Michael Thomas Margolis, M.D. (Dkt. 2031) at 13-15). As a non-expert in the field, it is all the more crucial that the biomaterial literature upon which Dr. Margolis relies be tailored to the actual material about which he opines—Prolene. But the Sternschuss article does not address Prolene mesh, the type of mesh at issue in this litigation, which contains special antioxidants; the article discusses only polypropylene mesh generally. Plaintiffs admit that Prolene is different than polypropylene in general due to its antioxidants. (Pls.' Resp. at 4). They try to salvage the

[1] Ethicon acknowledges the Court's ruling in Wave 1 that, notwithstanding the fact that Dr. Margolis is not a biomaterials expert, such qualifications were "not necessary to opine on the clinical properties of mesh." (Dkt. 2681 at 8).

Sternschuss article by insisting that it discusses antioxidants (Pls.' Resp. at 5), but they offer no proof that the Sternschuss study tested the polypropylene with the same type of chemical makeup as Prolene. This Court has previously excluded Dr. Margolis's opinions where he did not cite studies involving the device in question. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 523 (S.D. W. Va. 2014) (excluding Dr. Margolis's Xenform complication-rate opinion in part because he did not cite a single study involving Xenform slings). Furthermore, the study's authors state that antioxidants added to or present in polypropylene are "available for release into the body"—but they offer no link between antioxidants and degradation. (Dkt. 2169-3 at 29).

Plaintiffs attempt to bolster Dr. Margolis's deficient methodology with the opinions of Dr. Guelcher, another of Plaintiffs' experts. But Dr. Margolis himself does not rely on Dr. Guelcher—he relies on the Sternschuss article. The fact that Plaintiffs' best response is to extensively cite another Plaintiffs' expert demonstrates how manifestly unsound Dr. Margolis's methodology is when it comes to degradation. Plaintiffs cite Dr. Guelcher's opinions regarding primary and secondary additives and his opinion that such additives do not prevent oxidation *in vivo*, but Dr. Guelcher never explains ***how Prolene's additives*** are supposedly ineffective *in vivo.*

Furthermore, as Defendants pointed out in the opening brief, the Sternschuss article is rife with speculation regarding supposed degradation and other outcomes. (Defs.' Mem. at 7). Plaintiffs complain that the speculative statements Defendants pointed out in its opening brief were "cherry-pick[ed]," but this argument ignores the uncertainty that permeates the *entire* article: "[S]tabilizers [that are added during the manufacturing process] are in large part responsible for the tissue responses observed after implantation since they ***may diffuse*** from the polymer into tissue and cause a tissue reation"; "Generally we have no idea what was used in a particular mesh construct"; "Each [sterilization] process ***may potentially*** alter molecular structure

of [polypropylene] . . . . These reactions ***may be*** responsible for alterations in the mesh, which ***may ultimately lead*** to deep cracking of the mesh surface and subsequent mesh failure"; "[C]ertain substances, generally stabilizers, that are added to or present in [polypropylene] mesh are ***potentially*** toxic and available for release into the body"; "The implant ***may be*** more susceptible to the enzymes . . . that are produced in the acute inflammatory phase"; "Various factors ***may affect*** the rate and severity of polymeric implant oxidation"; "Continued inflammatory responses ***may lead*** to erosion or quiescent mesh contamination ***may be*** activated, causing overt infection of the [polypropylene]." (Dkt. 2169-3 at 28-31). The Sternschuss article is inherently speculative and cannot serve as a reliable basis for Dr. Margolis's degradation opinions.

Although Plaintiffs try to minimize the speculation that drives this article by pointing to the fact that the study's authors cited the Clavé study, which purported to find degradation in polypropylene, the Clavé study does not buttress the Sternschuss article or Dr. Margolis's opinions because even Clavé admitted that "[s]everal hypotheses concerning the degradation of the [polypropylene] are described below. None of these, particularly direct oxidation, could be confirmed in this study." *See* Ex. A attached hereto, at 266. This study, too, cannot support Dr. Margolis's opinions on degradation or oxidation.

CONCLUSION

For all of the foregoing reasons, as well as the reasons set forth in its memorandum of law, Ethicon respectfully requests the Court grant their Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
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ETHICON WAVE 3 CASES LISTED IN EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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